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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,800	01/31/2002	John T. McDevitt	5119-00543	6961

7590 03/28/2005

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EXAMINER

LAM, ANN Y

ART UNIT PAPER NUMBER

1641

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/072,800	Applicant(s) MCDEVITT ET AL.	
	Examiner Ann Y. Lam	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-459 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-459 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-93 and 100-147, drawn to a system for detecting an analyte in a fluid, classified in class 436, subclass 514.
- II. Claims 94-98, drawn to a system for detecting an analyte in a fluid, classified in class 436, subclass 518.
- III. Claim 99, drawn to a system for detecting an analyte in a fluid, classified in class 436, subclass 523.
- IV. Claims 148-152, drawn to a sensor array, classified in class 436, subclass 524.
- V. Claims 153-160, drawn to a sensor array, classified in class 436, subclass 532.
- VI. Claims 161-196, drawn to a method for forming a sensor array, classified in class 435, subclass 4.
- VII. Claims 197-252, drawn to a method of sensing an analyte, classified in class 435, subclass 7.1.
- VIII. Claims 253-263, drawn to a particle for detecting an analyte, classified in class 436, subclass 541.
- IX. Claims 264-277, drawn to a particle for detecting an analyte, classified in class 435, subclass 7.92.

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- X. Claims 278-300, drawn to a particle for detecting an analyte, classified in class 436, subclass 526.
- XI. Claims 301-308, drawn to a particle for detecting an analyte, classified in class 436, subclass 527. (Examiner assumes that claims 306 and 307, which appear to have clerical errors, are meant to be dependent on claim 301.)
- XII. Claims 309-341, drawn to a method of forming a sensor array, classified in class 435, subclass 7.92. (Examiner assumes that claims 310-341, which appear to have clerical errors, are meant to be dependent on claim 309.)
- XIII. Claims 342-374, drawn to a sensor array, classified in class 435, subclass 7.95.
- XIV. Claims 375-398, drawn to a method for forming a sensor array, classified in class 35, subclass 7.2.
- XV. Claims 399-421, drawn to a sensor array, classified in class 435, subclass 287.2.
- XVI. Claims 422-444, drawn to a sensor array, classified in class 435, subclass 287.3.
- XVII. Claims 445-450, drawn to a method of forming a sensor array, classified in class 435, subclass 286.1.
- XVIII. Claim 451, drawn to a method of forming a sensor array, classified in class 435, subclass 288.4.

- XIX. Claims 452, drawn to a sensor array, classified in class 435, subclass 287.1.
- XX. Claims 453, drawn to a method of sorting various sized particles, classified in class 435, subclass 288.5.
- XXI. Claim 454, drawn to a device for sorting various sized particles, classified in class 435, subclass 288.2.
- XXII. Claim 455, drawn to a method of placing an array of particles on a target, classified in class 435, subclass 287.1.
- XXIII. Claim 456, drawn to a method of forming a check valve, classified in class 137, subclass 1.
- XXIV. Claim 457, drawn to a check valve assembly, classified in class 137, subclass 315.01.
- XXV. Claim 458, drawn to a method of forming a check valve assembly, classified in class 137, subclass 803.
- XXVI. Claim 459, drawn to a check valve, classified in class 137, subclass 455.

The inventions are distinct, each from the other because of the following reasons:

Inventions (I-V, VIII-XI, XIII, XV, XVI, XIX) and (VII and XXII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the

instant case the product as claimed can be used in a materially different process of using that product such as one of the other claimed method of using the product.

Inventions XXI and (XX and XXII) are related as product and process of use.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as in one of the other groups of the method of using the product.

Inventions (VI, XII, XIV, XVII, XVIII) and (I-V, VIII-XI, XIII, XV, XVI, XIX, XX, XXI) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process, such as that in any of the other groups of the claimed method of making a sensor array.

Inventions (XXIII and XXV) and (XXIV and XXVI) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as

claimed can be made by another and materially different process, such as that in any of the other groups of the claimed method of making a check valve.

Inventions (I-V, VIII, IX-XI, XIII, XV, XVI, XIX,) and (XXI) and (XXIV, and XXVI) are unrelated and patentably distinct and separate inventions. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and they have different modes of operation, different functions or different effects, because Inventions I-V, VIII, IX-XI, XIII, XV, XVI, XIX are directed to a sensor array (or a device having a sensor array), and Invention XXI is directed to a device for sorting various sized particles, and Inventions XXIV and XXVI are directed to check valve.

Inventions I-III are unrelated and patentably distinct and separate inventions. The different inventions are not disclosed as capable of use together and they have different modes of operation or different functions or different effects because invention II requires a second particle and a second cavity whereas inventions I and III do not. Invention III requires a sensor array comprising at least one particle coupled to the sensor array, whereas invention I does not.

Inventions IV, V, XIII, XV, XVI, XIX are unrelated and patentably distinct and separate inventions. Invention IV requires a second particle within a second cavity, wherein the second particle comprises a reagent, wherein a portion of the reagent is removable from the second particle when contacted with a decoupling solution, whereas

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the other inventions do not. Invention V requires a particle coupled to a supporting member, whereas the other inventions do not. Invention XIII requires a flexible projection positioned over a portion of the cavity, whereas the other inventions do not. Invention XV requires a diameter of a particle to be smaller than the top opening of the cavity, whereas the other inventions do not. Invention XVI requires a second cavity formed in the substrate, whereas the other inventions do not. Invention XIX requires a flexible projection positioned over the cavity, whereas the other inventions do not.

Inventions VI, XII, XIV, XVII, XVIII are unrelated and patentably distinct and separate inventions. The inventions are not disclosed as capable of use together and they have separate modes of operations, such as any of the other method of forming a sensor array.

Inventions (VI, XII, XIV, XVII, XVIII) and (XXII, XXIV, XXVI) are unrelated and patentably distinct and separate inventions. They are not disclosed as capable of use together, and inventions VI, XII, XIV, XVII and XVIII are a method of making a sensor array, whereas inventions XXII is a method of using an array and inventions XXIV and XXVI are directed to a check valve assembly

Inventions VI and VII are unrelated and patentably distinct and separate inventions. The inventions are not disclosed as capable of use together and they have separate modes of operation because invention VI is directed to a method of forming a sensor array and invention VII is a method of sensing an analyte.

Inventions (VI, XII, XIV, XVII, XVIII) and (XXIII, XXV and XXVI) are unrelated and patentably distinct and separate inventions. The inventions are not disclosed as

capable of use together and they have separate modes of operation because invention VI is directed to a method of forming a sensor array and inventions XXIII and XXV are directed to a method of forming a check valve and invention XXVI is directed to a check valve.

Inventions VII and (XII, XIV, XVII, XVIII and XX-XXVI) are unrelated and patentably distinct and separate inventions. The inventions are not disclosed as capable of use together and they have separate modes of operation because invention VII requires monitoring a spectroscopic change of a particle as it passes over a sensor array, which is not required in the other claims.

Inventions XXII and (XX and XXIII-XXVI) are unrelated and patentably distinct and separate inventions. The inventions are not disclosed as capable of use together and they have separate modes of operation because invention XXII is directed to a method of placing an array of particles on a target, whereas invention XX is directed to a method of sorting various sized particles, and inventions XXIII-XXVI are directed to a method of forming a check valve, or the check valve device.

Inventions (XX and XXI) and (XXIII-XXVI) are unrelated and patentably distinct and separate inventions. The different inventions are not disclosed as capable of use together and they have different modes of operation or different functions or different effects because inventions XX and XXI are directed to a method of, or device for, sorting various sized particles whereas inventions XXIII-XXVI are directed to a check valve or a method of forming a check valve.

Inventions (I-V, VIII-XI, XIII, XV, XVI, XIX) and (XX, XXIII and XXV) are unrelated and patentably distinct and separate inventions. Invention I is directed to a sensor array (or a device having a sensor array), whereas inventions XX is directed to a method of sorting various sized particles, inventions XXIII and XXV are methods of forming a check valve assembly.

Inventions VIII-XI are unrelated and patentably distinct and separate inventions. Invention VIII requires a biopolymer coupled to a polymeric resin, which is not required in the other inventions. Invention IX requires probe molecule coupled to a biopolymer, which is not required in the other inventions. Invention X requires a receptor coupled to a polymeric resin by a first linker, which is not required in the other inventions. Invention XI requires a biopolymer coupled to a polymeric resin, which is not required in the other inventions.

Inventions XXIV and XXVI are unrelated and patentably distinct and separate inventions. The different inventions are not disclosed as capable of use together and they have different modes of operation, different functions or different effects, because invention XXIV requires a particle in a cavity wherein the diameter of the particle is smaller than a width of the bottom opening of the cavity, and wherein a flexible projection is configured to allow insertion of the particle in the cavity, whereas invention XXVI does not.

Inventions XXIII and XXV are unrelated and patentably distinct and separate inventions. The different inventions are not disclosed as capable of use together and they have different modes of operation, different functions or different effects, because

invention XXIII requires forming a second opening in a second mask, and also inserting a particle into a cavity of a substrate, whereas invention XXV does not. Invention XXV requires etching the substrate through the slits in the mask to form a cavity, whereas invention XXIII does not.

Inventions (XXIV and XXVI) and (XXIII and XXV) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process such as by one of the other claimed method of forming the check valve.

Inventions (I-III) and (IV, V, VIII-XI, XIII, XV, XVI, XIX) are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require a second particle positioned within a second cavity (as claimed in group IV), nor a particle coupled to a supporting member (as claimed in group V), nor a polymeric resin (as claimed in groups VIII-XI), nor a flexible resin (as claimed in group XIII), nor a cavity wherein the diameter of a particle is smaller than the top opening of the cavity and larger than the bottom opening of the cavity (as claimed in

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group XV), nor a second cavity formed in the substrate (as claimed in group XVI), nor a flexible projection positioned over a cavity (as claimed in group XIX). The subcombination has separate utility such as use for purification or separation purposes.

Inventions (IV, V, XIII, XV, XVI, XIX) and (VIII-XI) are related as combination and subcombination. The combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require a biopolymer (as claimed in group VIII), nor a polymeric resin, or a receptor or biopolymer coupled to a polymeric resin (as claimed in group IX, X, XI). The subcombination has separate utility such as use for separation or purification purposes.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for one group is not required for the other groups, restriction for examination purposes as indicated is proper.

II.

Moreover, if Applicant elects invention X, Applicant must further elect a species according to the following. This application contains a claim directed to the following patentably distinct species of the claimed invention:

claim 281, where R3, R4 and R5 independently represent hydrogen, alkyl, aryl, alky carbonyl, or alkoxy carbonyl, or R4 and R5 together represent a cycloalkyl group, are each species. (Applicant must chose one of these species.)

Also, in addition to election of one of the above species, Applicant must also elect one of the following species: claim 281, where R6 represents hydrogen, alkyl, aryl, alkyl carbonyl, or alkoxy carbonyl, are each species.

Also, Applicant must elect one of the following species: claim 281, where R7 represents alkyl, aryl, alkyl carbonyl or alkoxy carbonyl, are each species.

Also, Applicant must elect one of the following species: claim 281, where Y is a peptide or hydrogen, are each species.

And, Applicant must elect one of the following species: claim 281, where Z is a polynucleotide, or oligosaccharide or hydrogen, are each species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 278-380 and 282-300 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A.L.



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